

# PRE-APPLICATION CONSULTATION

## Specialized Program of Research Excellence (SPORE)

*Translational Research Program (TRP)*

*Division of Cancer Treatment and Diagnosis (DCTD)*

*National Cancer Institute (NCI)*

*National Institutes of Health (NIH)*

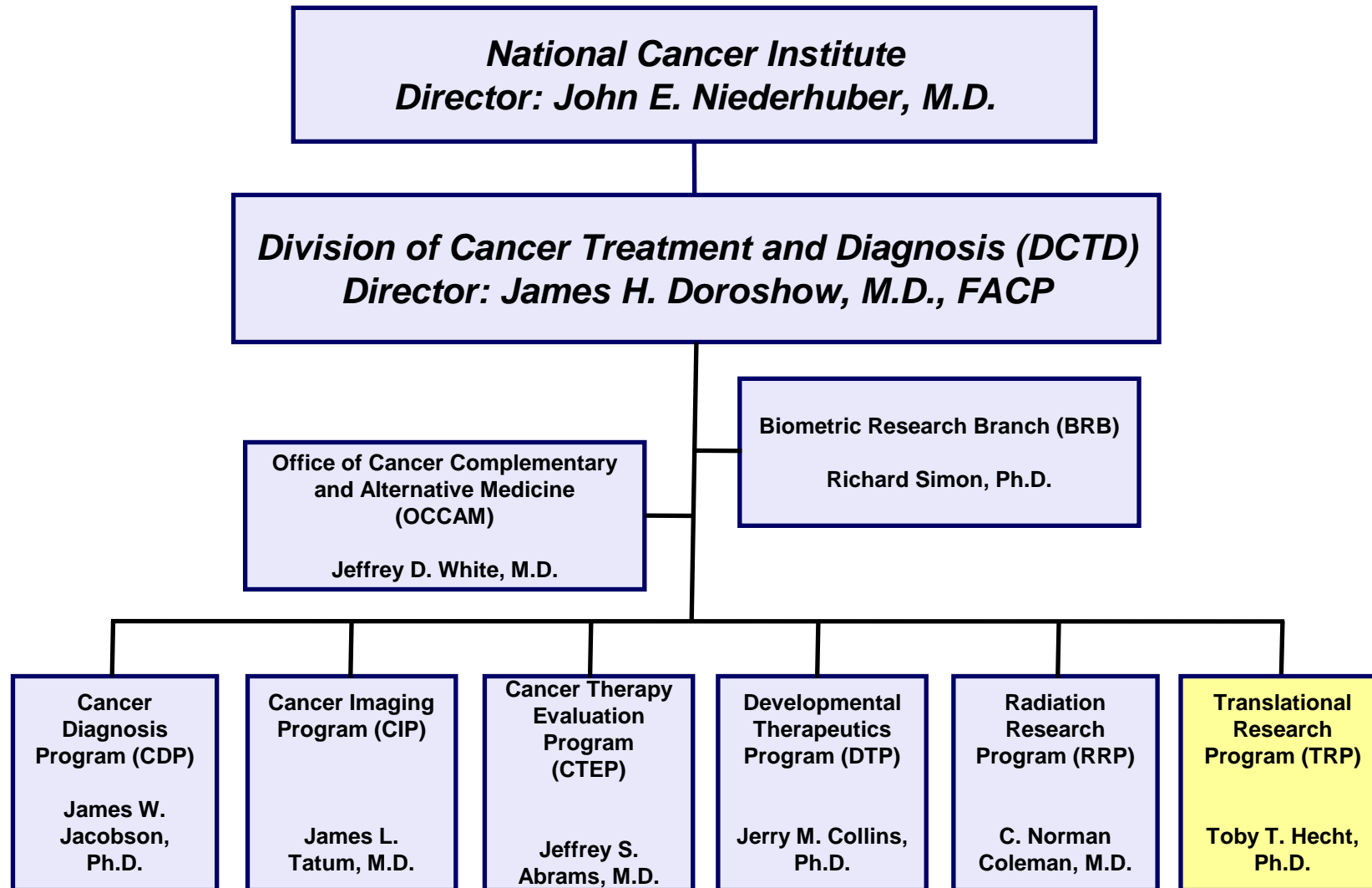
*6116 Executive Blvd, Suite 700, MSC 8347*

*Rockville, MD 20852*

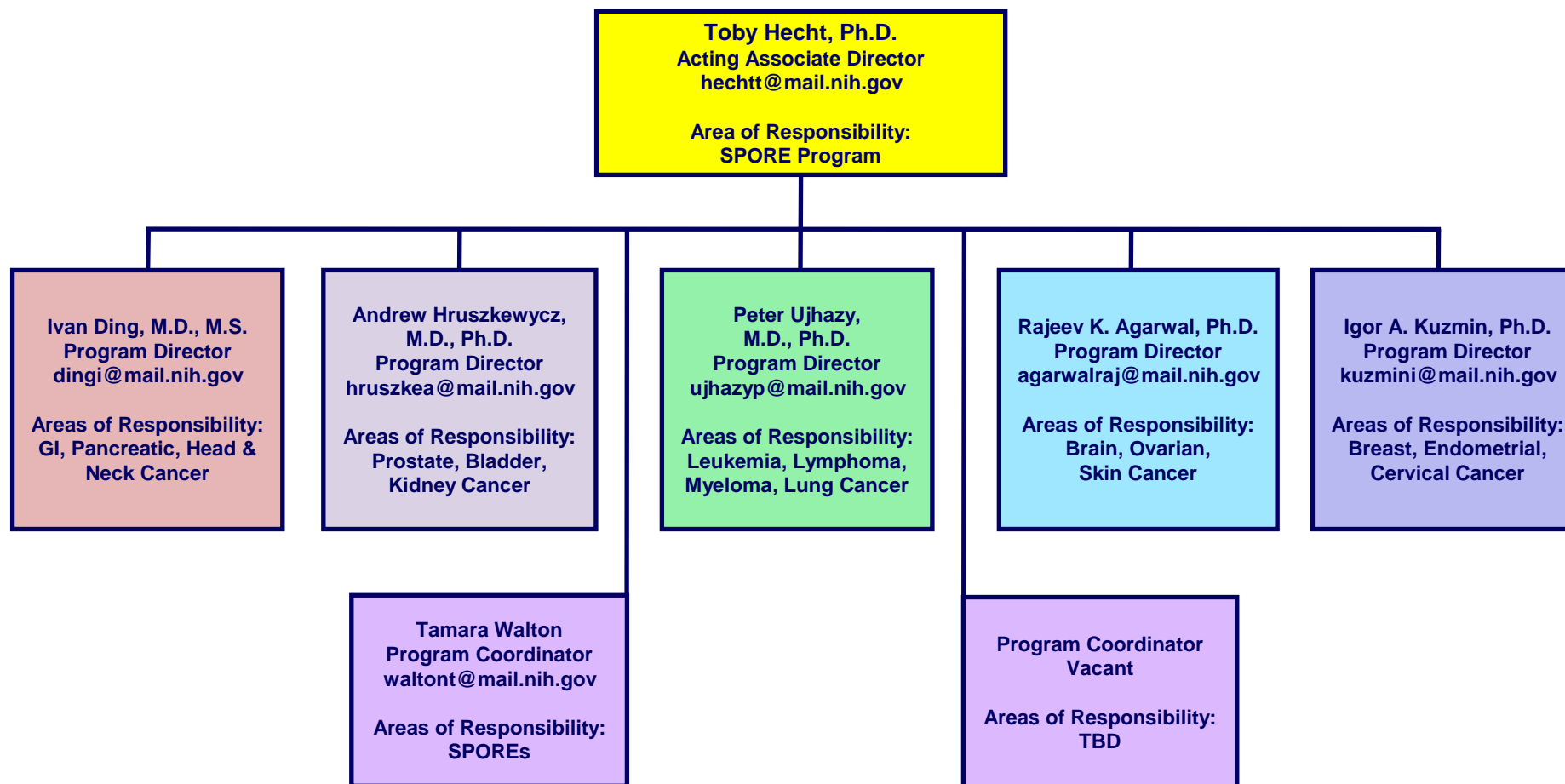
Tel: 301-496-8528; Fax: 301-402-5319; Internet: <http://spores.nci.nih.gov>



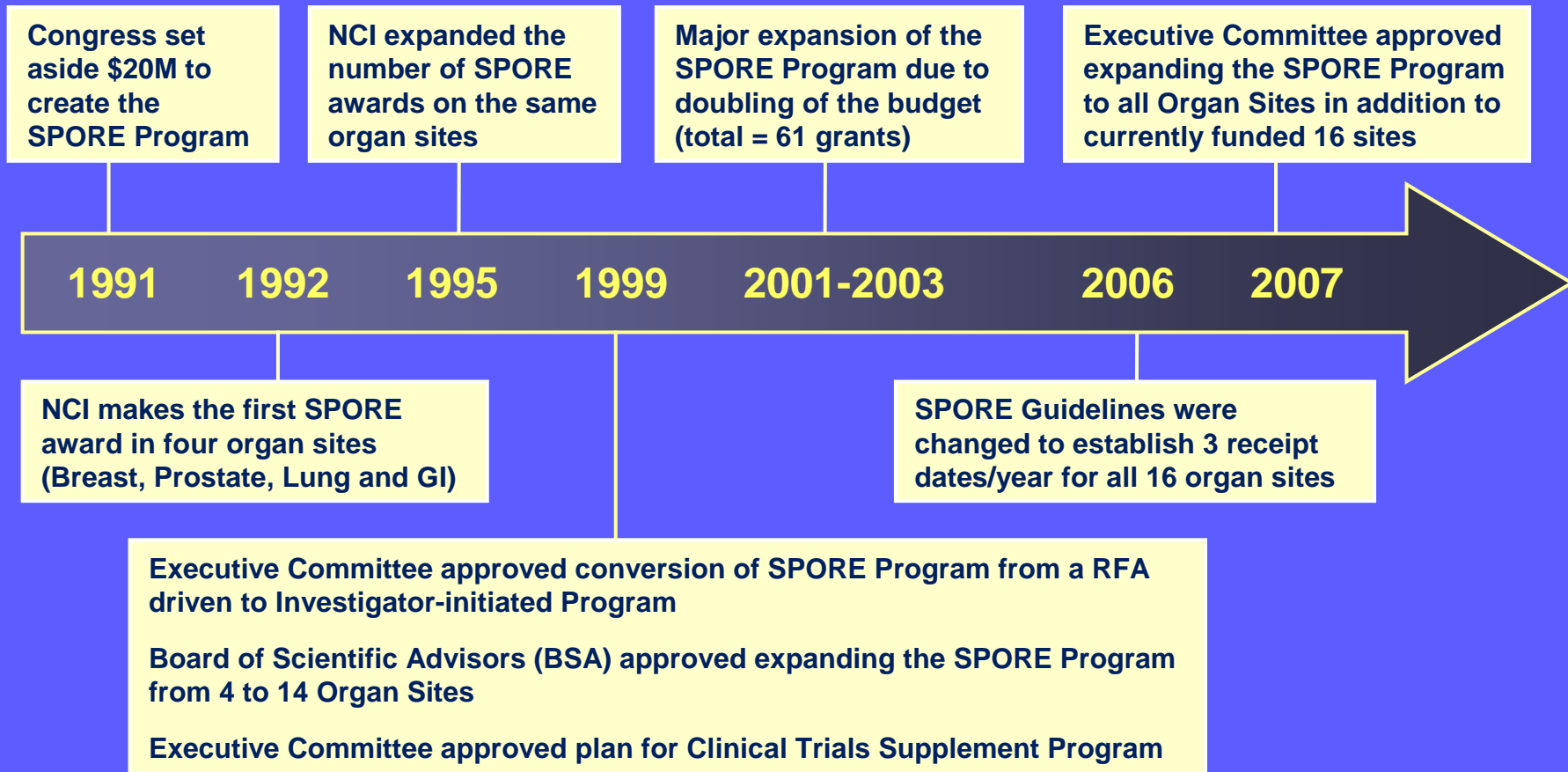
# NCI Organizational Chart



# Translational Research Program (TRP)



# SPORE: Major Events



# SPORE Program (1992-2007)

	← RFA →					← PAR →					
	1992-95	1996-98	1999	2000	2001	2002	2003	2004	2005	2006	2007
Breast	4	6	6	9	9	9	9	10	8	10	11
Prostate	2	3	3	4	8	11	11	11	11	8	7
Lung	2	3	3	3	6	6	7	7	7	5	6
Gastrointestinal	1	2	2	2	2	4	4	5	4	4	5
Ovary			4	4	4	4	4	5	4	4	4
Bladder					1	1	1	1	1	1	1
Skin					1	2	2	3	3	3	3
Brain						2	2	4	4	4	3
Head & Neck						3	3	4	4	4	3
Lymphoma						2	2	3	3	3	3
Endometrial							1	1	1	1	1
Cervical							1	1	1	1	1
Kidney							1	1	1	1	1
Leukemia							1	1	1	1	1
Myeloma							1	1	1	1	1
Pancreas							3	3	3	3	3
Total Programs*	9	14	18	22	31	44	53	61	57	54	54
Annual Budget	20M	30M	39M	48M	68M	112M	126M	135M	133M	125M	121M

\* This number excludes cost extensions

# **Policy Changes as of 2004**

- **NCI established a payline for all SPORes competing in a given fiscal year**
- **All organ sites compete for the same pool of available funds**

# Key Dates for SPORE Applications (PAR-08-020)

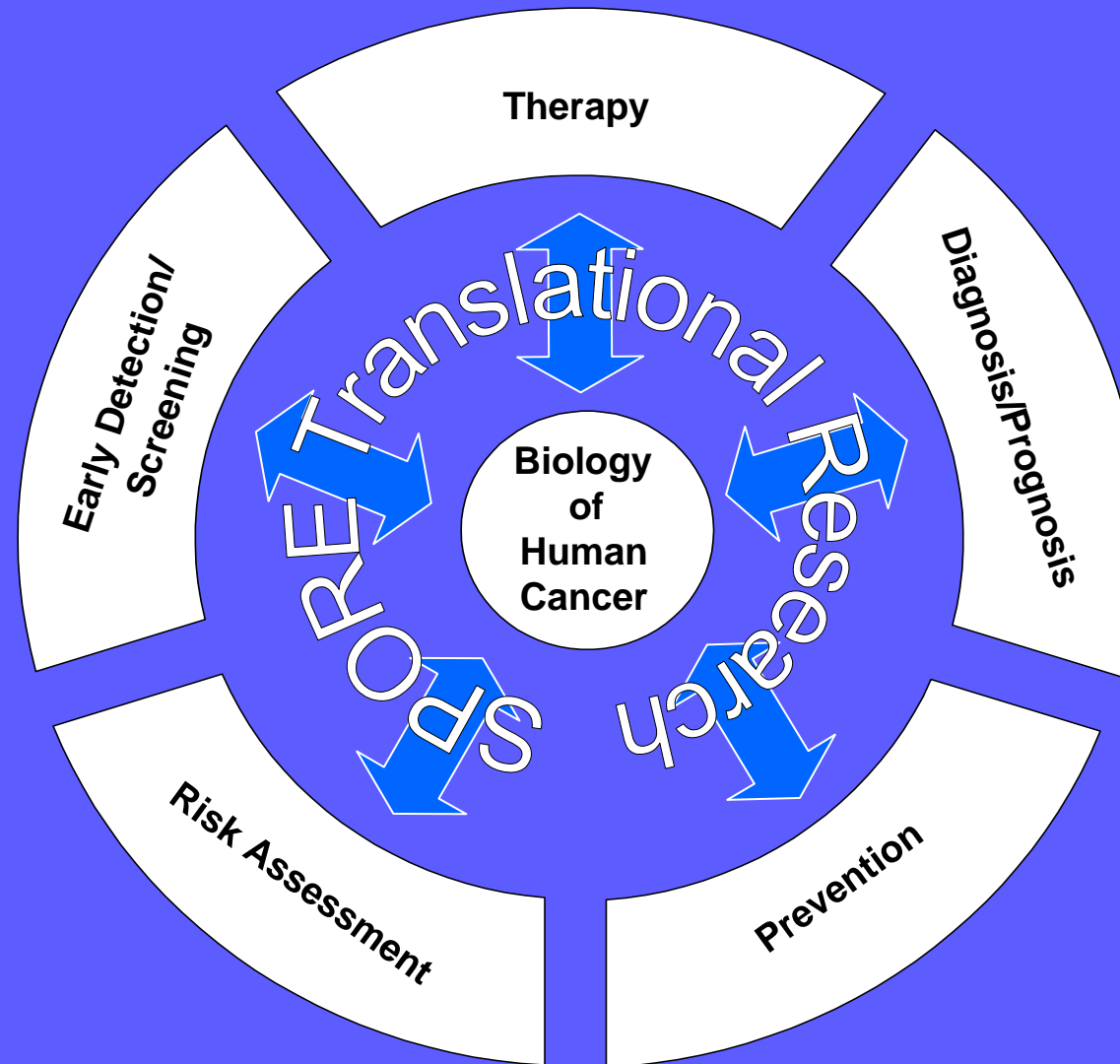
Letter Of Intent	Application Receipt	Peer Review	Council Review	Earliest Anticipated Start Date
Dec 22, 2007	Jan 23, 2008	May/June 2008	Sep/Oct 2008	Oct 2008
April 22, 2008	May 23, 2008	Sep/Oct 2008	Jan/Feb 2009	March 2009
Aug 22, 2008	Sep 23, 2008	Jan/Feb 2009	May/June 2009	July 2009
Dec 23, 2008	Jan 23, 2009	May/June 2009	Sep/Oct 2009	Oct 2009
April 21, 2009	May 22, 2009	Sep/Oct 2009	Jan/Feb 2010	March 2010
Aug 21, 2009	Sep 22, 2009	Jan/Feb 2010	May/June 2010	July 2010

# Translational Research in the SPORC Program

Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans *AND/OR* determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer



# Bi-Directional Translational Research



# SPORE Eligibility

- Domestic for profit and not for profit institutions
- Statement of institutional commitment
- Access to cancer patient population
- Basic and clinical research base
- Budget cap (\$2.5M total cost/year)

# SPORE General Features

- Inter-SPORE and NCI/NIH network collaborations (greater emphasis)
- Flexibility to realign resources
- Scientific outreach
- Peer review by Special Emphasis Panel
- Team concept
- Data/resource sharing

# **SPORE Budget-Cap**

- **\$2.5 million total cost for Year 1**
- **Up to 3% Cost of Living increase for Year 2 and subsequent years**
- **Applications that exceed these caps (including cost of living allowance) will be returned without review**

# SPORE Requirements

- Minimum of 4 translational research projects (including “required”)
- Shared cores (specimen core required; admin., stats, and clinical are optional)
- Statement of institutional commitment
- Intellectual Property Management Plan
- Data management plan
- Data and Resource sharing plan
- Developmental Research Program (DRP)
- Career Development Program (CDP)
- Commitment to attend and participate in SPORE Investigators’ Workshop
- Other provisions for NCI designated Cancer Centers (next 2 slides)

# **SPORE:**

## **Institutional Commitment**

- Letters of support from the institution
- Incorporation of the SPORE within its institutional priorities
- Matching funds for the DRP, CDP
- Facilitation and promotion of scientific progress
- Integration of SPORE activities with NCI-designated Cancer Center

## **Integration of SPORC with Institution or NCI-designated Cancer Center (CC)**

- **Principal Investigator: Prominent within institution or CC**
- **Lines of authority within institution or CC**
- **Organizational relationships**
- **Separate institutional commitment**
- **Augmentation of existing institution or CC resources: Cores**
- **Program coordination with institution or CC activities**

# **SPORE Director Qualifications**

- **Recognized scientific leader in the field**
  - ◆ Basic or clinical investigator
  - ◆ Provides leadership and direction to the SPORE
  - ◆ Oversees and conducts planning activities
  - ◆ May act as a project leader, co-investigator, or core director
- **Appropriate time commitment ( $\geq 25\%$ )**
- **Understands translational research objectives**
- **Identifies new translational research opportunities**



# Individual Research Projects

- Test novel translational ideas
- Project co-leaders – basic and applied scientists (minimum 2)
- Human application/endpoint within 5 years
- In some organ sites, at least one required project
- Human subjects (Data Safety Monitoring Plan, inclusion of women, children & minorities) and animal protections
- Interdisciplinary interactions (intra-project and with cores)
- Data and Resource sharing plan
- Consortium/Contractual arrangements

# Required Project

<u>Organ Site(s)</u>	<u>Includes the following cancers*</u>	<u>Required Project**</u>
1. Brain	Brain, but <i>not</i> peripheral nervous system (PNS) tumors	No
2. Breast	Breast	Yes
3. Gastrointestinal (GI)	Esophageal, Stomach, Intestinal, Liver, Pancreatic	Yes
4. Genitourinary (GU)	Bladder, Kidney, Testicular, but <i>not</i> Prostate	No
5. Gynecological (GYN)	Cervical, Endometrial, but <i>not</i> Ovarian	Yes (cervical) No (endometrial)
6. Head and Neck	Salivary, Larynx, Nasopharyngeal, Oral, Thyroid	Yes
7. Leukemia	Leukemia, myelodysplastic syndrome (MDS)	No
8. Lung	Lung	Yes
9. Lymphoma	Lymphoma (Hodgkin's, Non-Hodgkin's, chronic lymphocytic leukemia [CLL])	No
10. Myeloma	Myeloma, monoclonal gammopathies of undetermined significance (MGUS)	No
11. Ovary	Ovarian	Yes
12. Pancreas	Pancreatic	No
13. Prostate	Prostate	Yes
14. Skin	Skin	Yes
15. Other Cancer Sites	Contact Program Director/Official	

\* Not all inclusive; if proposing projects on other cancers, contact appropriate OSB program staff.

\*\* Applications requiring a project focused on early detection, screening, prevention, or population science.

# Required Project

- **Must focus on one of the following**
  - ♦ Early detection
  - ♦ Screening
  - ♦ Prevention (primary and secondary)
  - ♦ Population science
- **Those organ sites who do not have this requirement are encouraged to include a project focused on one of these four underutilized areas of science**

# SPORE Cores

- Integration with institutional cores
- Specimen core (required)
  - ◆ Parameters of collection and preservation; pertinent analytical considerations; essential pathological, clinical, family history information and linkage to databases, etc.
- Other specialized cores
  - ◆ Administrative
  - ◆ Clinical
  - ◆ Biostatistical
  - ◆ Bioinformatics
  - ◆ Others
- Cross-talk between cores and projects
- Data Management Plan

# Career Development Program (CDP)

- Plan for solicitation, review, and award
- Encourages new and established investigators to develop careers in translational cancer research
- Provides salary and other support
- Promotes mentoring of new investigators
- Recruitment plan for selection of candidates, including women and minorities
- Potential of promotion to full SPOR project

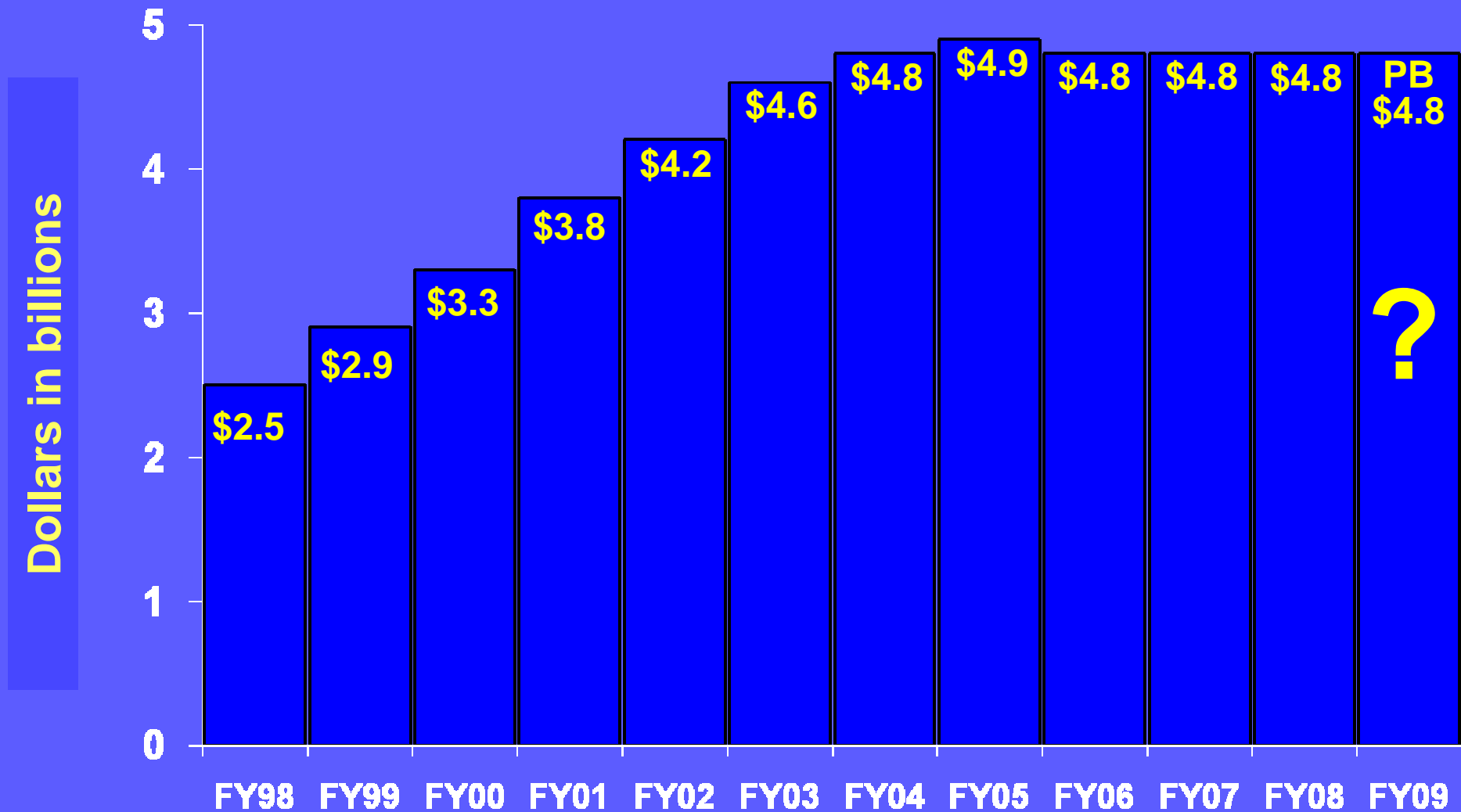
# Developmental Research Program (DRP)

- Plan for solicitation, review, and award
- Pilot projects that explore innovative ideas
  - ◆ Basic research projects
  - ◆ Early phase clinical research studies
- Takes advantage of new research opportunities
- Promotes collaborations among scientists at the same or different institutions
- Supports research proposed by *independent* investigators
- Potential of promotion to full SPORE project

# Annual SPORE Investigators' Workshop

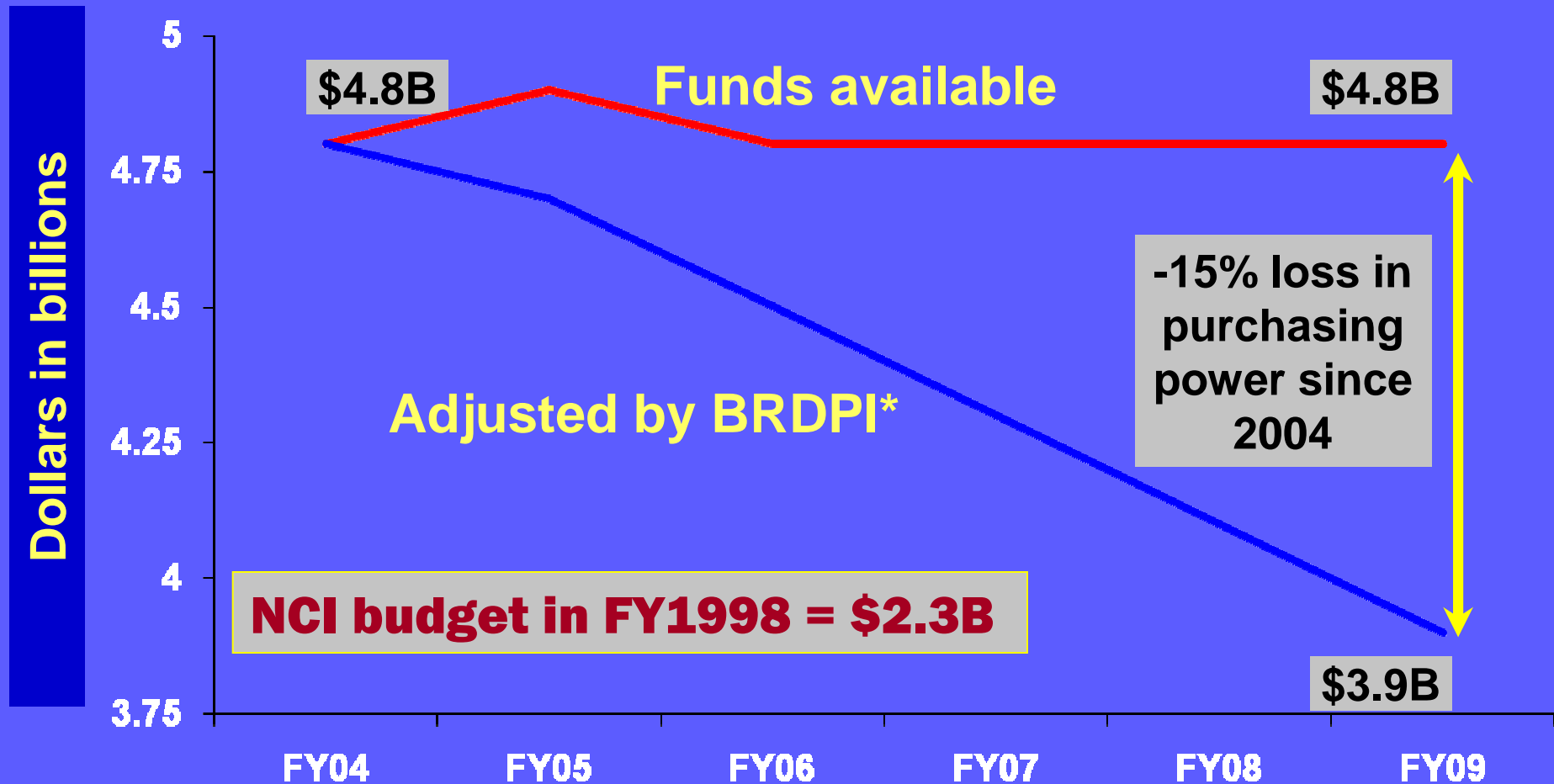
- Statement of commitment (within Admin. Core)
- Budget to fund 10 investigators to the Workshop (Admin. Core)
- Promote inter-SPORE collaborations
- Share new ideas, materials, and technologies
- Identify new research opportunities
- Establish research priorities that will Impact upon cancer detection, prevention, or treatment
- Resolve research needs by making recommendations to the NCI leadership
- Interact with patient advocates, NCI staff, and industry representatives

# NCI's Congressional Appropriations





# NCI's Challenge



\* BRDPI: Biomedical Research and Development Price Index  
(<http://officeofbudget.od.nih.gov>)

# SPORE Historical Success Rates

	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07	FY 08
Requested	49	56	46	17	25	39	40
Awarded	23	18	10	4	8	13	19
Success Rate	46.9%	32.1%	21.7%	23.5%	32.0%	48.7%	47.5%
% Ch. In Req.		14.3%	-17.9%	-63.0%	47.1%	40.0%	14.3%



New Program  
Guidelines

# SPORE Success Rates

	FY 04	FY 05	FY 06	FY 07	FY 08
Requested	46	17	25	39	40
Awarded	10	4	8	13	19
Success Rate (T1 & T2)	21.7%	23.5%	32.0%	33.3%	47.5%
Success Rate (T1 only)	17.9% (7/39)	18.2% (2/11)	16.6% (2/12)	15.8% (3/19)	31.3% (5/16)
Success Rate (T2 only)	42.8% (3/7)	33.3% (2/6)	46.1% (6/13)	50.0% (10/20)	58.3% (14/24 )

# Organ Sites Supported

	FY04	FY05	FY06	FY07	FY08
Bladder	1	1	1	1	1
Brain	3	4	4	4	4
Breast	9	10	10	11	10
Cervical	1	1	1	1	1
GI	5	4	4	5	5
Head & Neck	4	4	4	4	4 (1)*
Leukemia	1	1	1	1	1
Lung	8	7	7	7	8
Lymphoma	3	3	3	4	4
Myeloma	1	1	1	1	1
Ovarian	3	5	4	4	4
Pancreatic	3	3	3	3	2
Prostate	10	11	9	10	9
Renal (Kidney)	1	1	1	1	1
Skin	2	3	4	4	5
Uterine	1	1	1	1	0
<b>Total#</b>	<b>57</b>	<b>60</b>	<b>58</b>	<b>62</b>	<b>60 (61)</b>

#Includes all mechanisms

\*Supported by NIDCR

# Important web sites

- **SPORE:**

<http://spores.nci.nih.gov>

- **SPORE pre-application consultation:**

<http://spores.nci.nih.gov/applicants/guidelines/SPORE%20Orientation,%20May%202008.pdf>

- **SPORE program announcement:**

<http://grants.nih.gov/grants/guide/pa-files/PAR-08-020.html>

- **SPORE guidelines:**

[http://spores.nci.nih.gov/applicants/guidelines/SPORE\\_Guidelines\\_Final.pdf](http://spores.nci.nih.gov/applicants/guidelines/SPORE_Guidelines_Final.pdf)